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EXAMINER	
CHOI, FRANK I	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/854,802
Filing Date: May 14, 2001
Appellant(s): STANKOV, BOJIDAR M.

James V. Costigan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/6/2006 appealing from the Office action mailed 11/30/2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

5,879,710 Bromet et al. 03-1999

Lee et al., Controlled release of dual drug-loaded hydroxypropyl methylcellulose matrix tablet using drug-containing polymeric coatings, International Journal of Pharmaceutics (1999), Vol. 188, No. 1, pp. 71-80.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16-18, 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the formulation set forth in Example 1, does not reasonably provide enablement for other formulations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a tablet containing a slow release nucleus containing melatonin, hydroxypropylmethylcellulose (HPMC), lubricant, volume excipient and glidant and a fast release coating on said nucleus containing melatonin, HPMC, lubricant, volume excipient and glidant and method of inducing and maintaining sleep, where at least 95% of the melatonin in the nucleus is released within 5 hours in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius, where at least 95% of the melatonin in the cortex is released within 10 minutes in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius and at least with said tablet having .

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does not appear to disclose the claimed invention. Further, the prior art indicates that HPMC is a known retardant and dose of drug and amount and type of

excipients all have an effect on release rates (See Bromet et al. (US Pat. 5,879,710), Column 5, lines 1-5; Lee et al. (1999), pages 74-77). The Appellant argues that the prior art does not exhibit the release profile of the claimed invention as represented by Figure 1, yet the claimed invention also contains HPMC, a known retardant. As such, it appears that predictability in the art is low.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification appears to provide only one formulation that exhibits the release profile that the Appellant argues is the exhibited by the claimed invention.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that the only mentioned components are HPMC, melatonin, lubricant, volume excipient and glidant. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims, i.e. determining what combination of HPMC, melatonin, lubricants, volume excipients and glidants would result in the release profile claimed.

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to indicate that the slow release nucleus releases at least 95% of the melatonin within 5 hours in an oscillating tray containing gastric/ intestinal juice at 37 degrees Celsius and at least 95% of the melatonin in the cortex is released within 10 minutes in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius.

Said limitation includes within its scope that at least 95% of melatonin is released from the nucleus in less than 5 hours and 95% of the melatonin is released from the cortex in less than 10 minutes. The Appellant's disclosure only indicates that for the tablets tested 95% of the melatonin was released within the 5th hour not within five hours from the nucleus and in the tenth minute, not within ten minutes, at least 95% of the melatonin was released from the cortex (Pgs. 11, 12). Also, the Appellant has amended the claims to indicate that the fast release cortex also contains a lubricant, volume excipient and glidant. However, the Specification does not appear to indicate that the "cortex" contains lubricant or a glidant. The only example set forth contains, in addition to melatonin and HPMC, lactose, a bulking agent, i.e. volume, titanium bioxide, a pigment, and ethyl alcohol and water, solvents, which presumably are evaporated away in order to form the cortex (See Pg. 8, lines 15-23).

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (2) granulation, (4) addition of the retardant excipients, lubricants, volume and gliding excipients and (7) application of the melatonin solution under pressure on the tablets for the formation of the "cortex". Specification discloses that stages (2), (4) and (7) are essential for the preparation of the formulations which are the subject of the invention (Pg. 8, lines 27, 28).

(10) Response to Argument

Claim 16-18, 20-24 are rejected under 35 U.S.C. 112, first paragraph, lack of scope of enablement

Contrary to the Appellant's arguments, the Wands factors have been evaluated as indicated above. The Appellant argues that claims are specific to a specific material. However,

the claims are not limited to a specific material but include a combination of materials of which only two are specifically identified, i.e. melatonin and hydroxypropyl methylcellulose (HPMC). The other three components, lubricant, volume excipient and glidant are only identified by their function. The claims also permit the inclusion of other components to a greater extent by the use of the transitional phrase "comprising" and to a lesser extent by the use of the transitional phrase "consisting essentially of". The Appellant argues the recitation of other ingredients is made in terms that are specific of to materials or classes of materials that are well known and are exemplified in the specification and that the art of making controlled release formulations for oral administration has generated many thousands of patents, textbooks, etc. However, the issue is not whether the materials are well known or that there is a large body of art directed to general area of controlled release formulation. The issue is whether a single embodiment is sufficient to enable the claimed invention that is largely described by functional language and requires a specified release profile. The Examiner has provided evidence that the prior art indicates that HPMC is a known retardant and dose of drug and amount and type of excipients all have an effect on release rates (See Bromet et al. (US Pat. 5,879,710), Column 5, lines 1-5; Lee et al. (1999), pages 74-77). The Appellant has also argued that that the prior art does not exhibit the release profile of the claimed invention as represented by Figure 1 (Remarks (12/9/2002), yet the claimed invention also contains HPMC. The Appellant's evidence supporting enablement appears to be directed to the disclosed examples. However, as indicated above, the rejection herein is based on a scope of enablement rejection. The Examiner has already acknowledged that the Specification is enabled for the specified embodiment tested in the examples of the Specification. However, the claims are not limited to said embodiment. As such, citing to the disclosure of the same does not appear to provide evidence that supports the entire scope of the

claims. The unsupported argument that controlled release formulations are known in the art does not constitute evidence that the Specification enables the full scope of the claims. As such, since one of ordinary skill in the art could not readily determine what other combinations of components would result in the claimed release profiled based on the Specification, one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the claimed invention to the extent of the full scope of the claims.

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement

The Appellant argues that the reasons advanced by the Examiner are based on the use of the term "release the term melatonin within 5 hours .. and within 10 minutes". The Appellant argues that the reported performance criteria has to do with release of a stated time within a certain elapsed time and that it is not concerned with a release of less than the stated but only total release after a stated time. However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As such, the purported purpose of the reported performance criteria does not overcome the fact that the claim language is not supported by the Specification. Also, the rejection is not only based on the above limitation. As indicated above, the claims were amended to indicate that the fast release cortex also contains a lubricant, volume excipient and glidant. However, the Specification does not appear to indicate that the "cortex" contains lubricant or a glidant. The only example set forth contains, in addition to melatonin and HPMC, lactose, a bulking agent, i.e. volume, titanium bioxide, a pigment, and ethyl alcohol and water, solvents, which presumably are evaporated away in order to form the cortex (See Pg. 8, lines 15-23). The Appellant does not address this part of the rejection.

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements.

The Appellant argues that since the claims are directed to product and method of use claims, the Appellant is not required to recite process of making limitations in the claims. However, as indicated above, the Specification specifically indicates that stages (2), (4) and (7) are essential for the preparation of the formulations which are the subject of the invention (Pg. 8, lines 27, 28). The Appellant does not provide any evidence that the formulations may be prepared by a process that does not include said stages. The Appellant argues that claim 22 is dependent on claim 16, however, claim 22 is an independent claim and, as such, does not contain a lubricant as recited in claim 16. In any case, the rejection is based on the fact that the claims do not contain limitation directed to the stages (2), (4) and (7) and not only the presence of a lubricant. As such, the presence of a lubricant in claims 16 and claims dependent on claim 16 is not sufficient to overcome the rejection. As such, the claims are incomplete for omitting essential elements.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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